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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,425	02/19/2002	Harold G. Brown	2059-0103P	1812

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EXAMINER	
PRATS, FRANCISCO CHANDLER	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,425	BROWN ET AL.	
	Examiner	Art Unit	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,6-9,11-14,19,22-27,30-38,41,42,46-54,59,60,63-67 and 69-118* is/are pending in the application.

4a) Of the above claim(s) *3,8,9,13,24-27,30-35,52,60,63-65,67,96-111 and 116* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,6,7,11,12,14,19,22,23,36-38,41,42,46-51,53,54,59,66,69-95,112-115,117 and 118* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6-14-04, 2-24-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed June 14, 2004, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 1, 4, 5, 10, 15-18, 20, 21, 28, 29, 39, 40, 43-45, 55-58, 61, 62 and 68 have been cancelled.

Claims 71-118 have been added.

Claims 2, 3, 6-9, 11-14, 19, 22-27, 30-38, 41, 42, 46-54, 59, 60, 63-67 and 69-118 are pending.

Election/Restrictions

Applicant's election with traverse, in the paper filed December 15, 2003, of the group II invention, directed to glycosaminoglycan-containing compositions which do not contain essential oils, is acknowledged. Applicant's election of hyaluronic acid as the therapeutic compound is also acknowledged.

Applicant's additional argument, filed June 14, 2004, traversing the restriction requirement is noted. However, the restriction requirement in this application has been made final, and additional argument is inappropriate at this stage of prosecution. The additional argument will therefore not be addressed. Applicant is reminded that as amended the claims

continue to recite a multitude of products and methods, including a variety of different product forms which have different subclasses, and therefore could properly be subject to a restriction requirement. In view of the multitude of products and therapeutic treatments encompassed by the claims, ranging from animal treats to suppositories, it is respectfully submitted that the scope of the present examination of claims is in fact quite generous.

Claims 3, 8, 9, 13, 24-27, 30-35, 52, 60, 63-65, 67, 96-111 and 116 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. As noted above, applicant timely traversed the restriction (election) requirement in the paper filed December 15, 2003.

As amended 2, 6, 7, 11, 12, 14, 19, 22, 23, 36-38, 41, 42, 46-51, 53, 54, 59, 66, 69-95, 112-115, 117 and 118 read on compositions comprising a glycosaminoglycan in the absence of an essential oil, the invention elected by applicant, and encompass hyaluronic acid, the species of glycosaminoglycan elected by applicant. Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36-38, 41, 42, 46-51, 53, 54, 59, 66, 69-95, 112-115, 117 and 118 are

therefore examined on the merits, to the extent they read on compositions comprising hyaluronic acid.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on February 24, 2004, and June 14, 2004, were filed after the mailing date of the first office action on February 12, 2004. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

With respect to the IDS filed on October 11, 2002, note that all references were considered, the form initialed, and a copy sent to applicant along with the office action of February 12, 2004.

Claim Rejections - 35 USC § 112

Claims 7, 12, 14, 22, 23, 42, 50, 51, 59, 66, 72, 92, 93, 95 and 112-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitations "high and low molecular weight ranges" and "low purity" are indefinite because they are relative terms

whose metes and bounds are unclear because the relative terms "high" and "low" have an entirely subjective meaning. Because the subject matter considered "high" or "low" by one practitioner would not necessarily be the same as the subject matter considered "high" or "low" by another practitioner, these terms fail to clearly delineate between claim-encompassed subject matter and non-claim-encompassed subject matter as required by the statute.

Claim 22 is indefinite because the proviso regarding the use of chondroitin sulfate "as the sole glycosaminoglycan" makes no sense in the context of claim 22, because claim 22 requires hyaluronic acid in the composition. Because hyaluronic acid must be in the composition, chondroitin sulfate can never be "the sole glycosaminoglycan" in the composition.

Claim 112 and its dependents are considered indefinite becuase the recitation "effective amount of hyaluronic acid" does not define any intended effect for the hyaluronic acid. It is therefore unclear what an effective amount actually is.

All of applicant's argument regarding the § 112, second paragraph, rejection over "high" and "low" has been fully considered but is not persuasive of error. Applicant asserts that the terms at issue are clearly defined in the specification, quoting the specification in support thereof.

However, reference to the quoted portions of the specification make it clear that there is no single definition for any of the clearly relative terms recited in the claims. Instead, the quoted portions of the specification provide multiple possible meanings as well as examples or "preferable" meanings for the terms at issue. In the absence of a single clear definition in the specification, it is improper to read definitions from the specification into the claims. The fact that applicant fails to point to a single definition in the specification underscores the fact that the specification provides no clear definition which delineates between claimed subject matter and unclaimed subject matter. In short, if applicant desires to provide a concrete meaning for these terms, those meanings must appear in the claims.

Claim Rejections - 35 USC § 102

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36-38, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 73-76, 78, 80, 81, 91-95, 112, 117 and 118 are rejected under 35 U.S.C. 102(b) as being anticipated by Balazs (U.S. Pat. 4,303,676).

Balazs discloses a product comprising a low molecular weight hyaluronate fraction having a molecular weight of 10,000 to 200,000, a high molecular weight hyaluronate fraction having

a molecular weight from 1 to 4.5 million, 50 to 400% protein (based on the weight of the hyaluronate), and water. See column 1, line 64 through column 2, line 6. In a preferred embodiment the product, designated as "HPE", is a visco-elastic liquid containing about 1% sodium hyaluronate, 0.5 to 1.5% protein and 97.5 to 98.5% water. See column 4, lines 59-68. In view of the protein present in the composition, the requirement of "low purity" is clearly met. Because the claimed ingredients are present in the claimed concentrations, a holding of anticipation is required.

It is noted that the composition is not designated as being for oral administration. However, as discussed above, the HPE composition disclosed by Balazs is in liquid form, and therefore clearly can be administered orally, and therefore can be considered a food or drink. Moreover, the product clearly can be absorbed mucosally. Note that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re*

Casey, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Because Balasz's compositions can be administered orally, and because they are in the form of food and drink, as those terms are properly construed most broadly, a holding of anticipation is clearly required.

All of applicant's argument regarding the holding of anticipation over Balazs has been fully considered but is not persuasive of error. In the instant case, contrary to applicant's argument, as described by the reference, the product is clearly a non-toxic liquid. See Balazs, at column 4, lines 26-32, disclosing that because of the source material, the product is considered to be non-toxic:

> HPE is prepared from the skin of animals which have been slaughtered for human consumption. During the purification procedure no toxic chemicals are used, and all other chemicals which are used during this process are removed. Therefore oral toxicity studies are deemed not to be necessary.

Because it is a non-toxic liquid, the product is therefore clearly drinkable. Because the product is drinkable, the product anticipates those claims directed to drinks, drink mixes, food, mouthwash, gargle, vaporizer liquid, and ingestable nutritional supplements. Applicant's argument also ignores the fact that the claims also encompass "mucosally absorbable" compositions, a limitation clearly met by Balazs.

As discussed above, the evidence for anticipation is overwhelming. Significantly, applicant provides no factual evidence whatsoever, e.g. evidence of toxicity, to refute the holding of anticipation. Note specifically that on the current record the only way of overcoming such a clear holding of anticipation is factual proof that the rejection is in error. *See* MPEP § 2112, disclosing that once a proper holding of anticipation is made, the burden shifts to applicant to demonstrate an unobvious difference between the claims and the prior art. *See also, In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) ("the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product"). Because applicant has not demonstrated any difference between the claimed products and the prior art products, the rejection of record clearly must be maintained.

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36-38, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 73-76, 78, 80, 81, 91-95, 112, 117 and 118 are rejected under 35 U.S.C. 102(b) as being anticipated by Turley et al (WO 97/25051).

Turley discloses orally administrable hyaluronic acid compositions. See abstract. The preferred products are

disclosed as being in liquid drink form. See, e.g., page 12, lines 20-22. In view of the protein present in the composition (see pages 7-11 disclosing the makeup of the compositions) the requirement of "low purity" is clearly met. Because the claimed ingredients are present in the claimed concentrations, a holding of anticipation is required.

It is noted that applicant has not addressed argument to this ground of rejection required by applicant's amendment. However, unlike the situation with Balazs, Turley explicitly rather than inherently discloses an orally administrable composition.

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36-38, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 73, 84, 90, 92-95, 112, 117 and 118 are rejected under 35 U.S.C. 102(b) as being anticipated by Gallina (WO 92/22585).

Gallina discloses rectally administrable hyaluronic acid compositions. See abstract. The products are disclosed as being suitably "incorporated into numerous types of gels, creams, ointments, lotions, pastes, salves, liquids, and/or supppsitory vehicles." See page 6, lines 17-20. In view of the various additional agents which may be present in the composition (see page 7, lines 7-16 disclosing the adjuvants

suitable for the compositions) the requirement of "low purity" is clearly met. Because the claimed ingredients are present in the claimed concentrations, and in the claimed forms, and because the composition is absorbed by a mucosae, a holding of anticipation is required.

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36-38, 41, 42, 46-51, 53, 54, 59, 66, 69, 70, 73, 76, 77, 82-84, 92-95, 112, 117 and 118 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 9-262057.

JP '057 discloses "[b]ad breath deodorant foods [are] composed of polysaccharides having carboxyl group, particularly alginic acid, ***hyaluronic acid***, pectic acid, their salts or esters, and/or carboxymethylcellulose (CMC), ***and held on carriers of candy, gum or gelatin."*** See attached English language Derwent abstract (emphasis added).

Because JP '057 discloses a composition comprising the claimed ingredients, a holding of anticipation is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 6, 7, 11, 12, 14, 19, 22, 23, 36-38, 41, 42, 46-51, 53, 54, 59, 66, 69-95, 112-115, 117 and 118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turley et al (WO 97/25051).

As discussed above, because Turley explicitly discloses orally administrable compositions of hyaluronic acid in drink form, Turley is considered to anticipate numerous embodiments recited in applicant's claims. However, Turley differs from the

certain embodiments recited in the claims under examination by failing to explicitly discloses the use of all of the claimed oral administration forms, including tablets, capsules and food supplements, including animal treats, as the physical form of the orally administrable hyaluronic acid compositions disclosed therein. However, in view of Turley's clear disclosure that oral administration was a suitable method of giving hyaluronic acid to patients, the artisan of ordinary skill would have considered all of the claimed oral vehicles obvious forms of administering the hyaluronic acid compositions of Turley. A holding of obviousness is therefore required.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action

is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP